

### **III. REMARKS**

Claims 2-6, 8-10, 29, and 30 are pending in this application. In the Office Action, claims 2-6, 8-10, 29, and 30 are rejected. By this Amendment, claims 2-4 and 8-10 are amended.

Applicant does not acquiesce in the correctness of the rejections or objections and reserves the right to present specific arguments regarding any rejected or objected-to claims not specifically addressed. Further, Applicant reserves the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application.

Reconsideration of the above rejections and objections in view of the following remarks is respectfully requested. Reconsideration in view of the following remarks is respectfully requested.

In the Office Action, claims 4 and 10 are rejected under 35 U.S.C. § 112, ¶ 2 as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Specifically, the Office alleges that the claims are confusing because they depend from claim 29, which uses the closed language “consisting essentially of,” which “does not permit the addition of other ingredients to the composition, such as the flowable gel of claim 4 or the opiate of claim 10.” Office Action at 3. Applicant has amended each of claims 2-4 and 8-10 and asserts that, as amended, each of claims 4 and 10 clearly distinguish between the cannabinoid and the cannabinoid composition. Specifically, Applicant asserts that amended claim 4 makes clear that the flowable gel is a component of the occlusive body rather than the cannabinoid composition and that amended claim 10 similarly makes clear that the opiate is delivered with the cannabinoid composition rather than as part of the cannabinoid composition. Accordingly, Applicant respectfully requests withdrawal of the rejection.

In the Office Action, claims 6, 8, 9, 29, and 30 are rejected under 35 U.S.C. 102(b) over P.C.T. Publication No. WO 99/53917 to Hampson *et al.* Specifically, the Office alleges that the Hampson *et al.* reference teaches “a method for using cannabidiol in subjects who have been exposed to cancer chemotherapy or who have HIV. The cannabidiol can be administered transdermally or topically. The symptoms of chemotherapy are inherent from a specific chemotherapeutic agent.” Office Action at 3 (internal citations omitted). This rejection is respectfully traversed. Applicant asserts that the Office is misinterpreting the teachings of the Hampson *et al.* reference. The Hampson *et al.* reference does not teach a method “for relieving symptoms associated with illness or discomfort associated with the treatment of illness” as recited in claim 29, from which all other rejected claims depend. Rather, the Hampson *et al.* reference teaches methods of using cannabinoids as antioxidants.

The invention provides antioxidant compounds and compositions, such as pharmaceutical compositions, that include cannabinoids that act as free radical scavengers for use in prophylaxis and treatment of disease. The invention also includes methods for using the antioxidants in prevention and treatment of pathological conditions such as ischemia (tissue hypoxia), an in subjects who have been exposed to oxidant inducing agents such as cancer chemotherapy, toxins, radiation, or other sources of oxidative stress. Hampson *et al.*, page 9, line 36 – page 10, line 4 (emphasis added).

Thus, the Hampson *et al.* reference cannot reasonably be read to teach methods “for relieving symptoms associated with illness or discomfort associated with the treatment of illness.” In fact, the Hampson *et al.* reference does not teach methods for the treatment of symptoms or discomfort at all. Accordingly, Applicant respectfully requests withdrawal of the rejection.

In the Office Action, claims 2-6, 8-9, 29, and 30 are rejected under 35 U.S.C. 102(e) over United States Patent No. 6,328,992 to Brooke *et al.* Applicant notes, however, that in its rejection, the Office makes no mention of how the Brooke *et al.* reference anticipates either

claim 29 or claim 30 and requests that the Office state with particularity its basis for the rejection of these claims. Nevertheless, this rejection is respectfully traversed. Applicant submits that the Brooke *et al.* reference fails to teach each and every feature of the claimed invention.

Specifically, as indicated in claim 29, the present invention provides “a cannabinoid composition consisting essentially of cannabidiol” (emphasis added). Contrary to the assertions of the Office, such a feature is not taught by the Brooke *et al.* reference. Specifically, as previously argued, the Brooke *et al.* reference at best only teaches administration of mixtures of Delta8-THC, Delta9-THC and Cannabinol and CBD. *See, e.g.*, column 6, lines 25-34, where the specification teaches preparation of cannabis by extraction of oils from a cannabis plant. *See also* the Examples (columns 7-9), wherein the specification discloses only compositions comprising 3% Delta8-THC, 30% Delta9-THC, 35% CBD, and 32% Cannabinol.

In response to Applicant’s earlier arguments and in making the above rejection, the Office asserts that “the expression ‘consisting essentially of’ does not exclude the presence of other components that does [sic] not materially alter the composition.” Office Action at 7. Applicant notes, however, that in rejecting claims 4 and 10 under 35 U.S.C. § 112 ¶ 2, described above, the Office asserts that the same language “does not permit the addition of other ingredients to the composition, such as the flowable gel of claim 4 or the opiate of claim 10.” Office Action at 3. Applicant respectfully requests clarification of the Office’s seemingly conflicting position as to how the flowable gel of claim 4 and the opiate of claim 10 materially alter a composition consisting essentially of cannabidiol but Brooke *et al.*’s inclusion of Delta8-THC, Delta9-THC, and Cannabinol does not similarly alter such a composition.

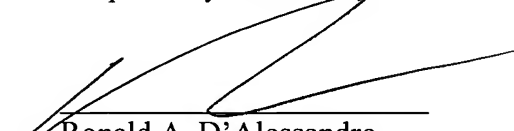
Applicant submits that the mere potential presence of Delta8-THC, Delta9-THC or cannabinol is not the same as providing a cannabinoid composition consisting essentially of

cannabidiol, as presently claimed. Accordingly, Applicant respectfully requests withdrawal of the rejection.

In the Office Action, claim 10 is rejected under 35 U.S.C. § 103(a) over either of the Hampson *et al.* reference or the Brooke *et al.* reference in view of United States Patent Application Publication No. 2003/0158191 to Travis. In addition, claims 2-5 are rejected under 35 U.S.C. § 103(a) over the Hampson *et al.* reference in view of the Brooke *et al.* reference. These rejections are respectfully traversed. For each of the reasons given above with respect to the Hampson *et al.* reference and the Brooke *et al.* reference, Applicant respectfully requests withdrawal of the rejections.

In view of the foregoing, Applicant respectfully requests withdrawal of the rejection, and allowance of the application. Should the Examiner require anything further from Applicant, the Examiner is invited to contact Applicant's undersigned representative at the number listed below.

Respectfully submitted,



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